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Appl. No. 10/557,196
December 22, 2008

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application:

1 (currently amended). ~~The use of~~ Method of aiding an individual to wake refreshed after sleeping, comprising administering to the individual an aid comprising as active ingredient triprolidine or a salt or hydrate thereof, in combination with at least one further active pharmaceutical agent, as active ingredient of an aid to waking refreshed after sleeping.

2-4 (canceled).

5 (currently amended). ~~The use of~~ Method of aiding an individual to sleep and also to wake refreshed after sleeping, comprising administering to the individual a sleep aid comprising as active ingredient triprolidine or a salt or hydrate thereof, in combination with at least one further active pharmaceutical agent, as active ingredient of a sleep aid which also enables an individual to wake refreshed after sleeping.

6-7 (canceled).

8 (withdrawn). The use of triprolidine or a salt or hydrate thereof, in combination with at least one further active pharmaceutical agent, as active ingredient in the manufacture of a composition for inducing, prolonging and/or enhancing sleep

and/or sleep quality.

9 (withdrawn). A method for the treatment or prevention of grogginess, drowsiness or lethargy on waking from sleep in a mammal comprising the administration to the mammal in need thereof of a non-toxic effective dose of triprolidine or a salt or hydrate thereof in combination with at least one further active pharmaceutical agent prior to the desired sleeping time.

10 (withdrawn). A method for enabling an individual to wake refreshed after sleeping comprising the administration to the individual in need thereof and prior to the desired sleeping time of a non-toxic effective dose of triprolidine or a salt or hydrate thereof in combination with at least one further active pharmaceutical agent.

11 (withdrawn). A method for aiding an individual's sleep and for also enabling the individual to subsequently wake refreshed after sleeping comprising the administration to the individual in need thereof and prior to the desired sleeping time of a non-toxic effective dose of triprolidine or a salt or hydrate thereof in combination with at least one further active pharmaceutical agent.

12 (withdrawn). A method of treating sleep of a person suffering from a sleep disorder, which method comprises administration of an effective dose of triprolidine or a salt or hydrate thereof, in combination with at least one further active pharmaceutical agent, as active ingredient to such a person.

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13 (withdrawn). A method for inducing, prolonging and/or enhancing sleep, which method comprises administration of an effective dose of triprolidine or a salt or hydrate thereof, in combination with at least one further active pharmaceutical agent, as active ingredient to a person desirous of achieving sleep.

14 (original). A waking refreshed aid comprising triprolidine or a salt or hydrate thereof, in combination with at least one further active pharmaceutical agent, as active ingredient in association with a pharmaceutically acceptable carrier therefor and instructions for administration thereof at or just before the desired sleeping time.

15 (withdrawn). A pharmaceutical formulation for the treatment or prevention of grogginess, drowsiness or lethargy on waking after sleeping, comprising triprolidine or a salt or hydrate thereof, in combination with at least one further active pharmaceutical agent, as active ingredient in association with a pharmaceutically acceptable carrier therefor and instructions for administration thereof at or just before the desired sleeping time.

16 (original). A pharmaceutical formulation for enabling an individual to wake more refreshed after sleeping, comprising triprolidine or a salt or hydrate thereof, in combination with at least one further active pharmaceutical agent, as active ingredient in association with a pharmaceutically acceptable carrier therefor and instructions for administration thereof at or just before the desired sleeping time.

17 (currently amended). ~~The use of triprolidine or a salt or hydrate thereof~~
method as claimed in claim 1, wherein ~~the~~ said at least one further active
pharmaceutical agent is ~~intended to be used in the~~ for treatment of a condition having
sleep disorder as a symptom or potential symptom.

18 (currently amended). ~~The use of triprolidine or a salt or hydrate thereof~~
method as claimed in claim 1, wherein the said at least one further active
pharmaceutical agent is selected from: the group consisting of an active agent used in
the treatment of pain relief, migraines, allergies, colds, flu, coughs or anxiety; an active
agent used as an anaesthetic, antiviral agent, antidepressive agent, decongestant or
disinfectant; ~~or~~ and an active agent used in women's health.

19 (currently amended). ~~The use of triprolidine or a salt or hydrate thereof~~
method as claimed in claim 1, wherein ~~the~~ said at least one further active agent is
independently selected from any one or more of the following agents or their active salts
or hydrates: Ibuprofen, Fluribiprofen, Ketoprofen, Aspirin, Paracetamol, Aceclofenac,
Codeine, Naproxen, Indomethacin, Diclofenac, Cox II, Meloxicam, Nitric oxide, Caffeine,
Acrivastine, Cetirizine, Loratadine, Fexofenadine, Terfenadine, Beclomethasone,
Hydrocortisone, Triptan, Almotriptan, Rizatriptan, Naratriptan, Sumatriptan,
Zolmatriptan, Domperidone, Acetylcysteine, Menthol, Ambroxol, Carbocisteine,
Dextromethorphan, Guaiphenesin, Ipecacuanha, Phenylpropanolamine, Liquorice,
Marshmallow, Squill, Honey, Glycerine, Aniseed, Benzocaine, Lidocaine, Amantadine,

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Aciclovir, Famciclovir, Ganciclovir, Rimantadine, Penciclovir, Tribavirin, Valaciclovir, Neuraminidase inhibitors, Zanamir, Oseltamir, Benzalkonium chloride, Cetylpyridinium chloride, Dichlorobenzyl alcohol, Amylmetacresol, Dequalinium chloride, Hexylresorcinol, Eucalyptus oil, Thymol, Calamine, Propranolol, Chamomile, Hops, Passion flower, Valarian, Melatonin, Eucalyptus, Phenylephrine, Pseudoephedrine, Cranberry and Bisphosphonates.

20 (currently amended). ~~The use of triprolidine as a salt or hydration thereof~~
method as claimed in claim 19, wherein the said active pharmaceutical agent is independently selected from any one or more of the following agents or their active salts or hydrates Ibuprofen, Flurbiprofen, Cox II such as meloxicam, triptans, Domperidone, Ambroxol, Dextromethorphan, Guaiphenesin, Lidocaine, Amantadine, Hexylresorcinol, dcb, amc, Propranolol, pseudoephedrine, and Bisphosphonates or and a pharmaceutically acceptable salt of any of the foregoing.

21 (currently amended). ~~The use of triprolidine or a salt or hydrate thereof~~
method as claimed in claim 1, wherein the further active pharmaceutical agent may be combined with triprolidine in a single dosage form or in a pharmaceutical pack containing at least two dose forms, one being triprolidine and the other being the said further active pharmaceutical agent.

22 (canceled).

23 (currently amended). ~~The use of triprolidine or a salt or hydrate thereof~~
method as claimed in claim 1, wherein the dosage of the said further pharmaceutically
active agent is one suitable for the treatment selected.

24 (currently amended). The ~~use~~ method as claimed in claim 1, wherein the
dose of triprolidine administered to the user prior to sleeptime is between 0.01mg and
20mg.

25 (currently amended). The ~~use~~ method as claimed in claim 1, wherein the
dose of triprolidine administered to the user before sleeptime is up to 20mg.

26 (currently amended). The ~~use~~ method as claimed in claim 1, wherein the
said further active pharmaceutical agent may include, without limitation, antacids,
analgesics, anti-inflammatories, antibiotics, laxatives, anorexics, antiasthmatics,
antidiuretics, antiflatulents, antimigraine agents, antispasmodics, additional sedatives,
antihyperactives, tranquilizers, antihistamines, decongestants, betablockers,
antidepressives, hormones and combinations thereof.

27 (canceled).

28 (withdrawn). The method as claimed in claim 9, wherein the dose of
active ingredient of triprolidine administered is between 0.01 and 20mg.

29 (withdrawn). The method as claimed in claim 9 wherein the dose of active ingredient of triprolidine administered is up to 20mg.

30 (withdrawn). The pharmaceutical formulation as claimed in claim 15, wherein the instructions for administration instruct a single dose comprising active ingredient of triprolidine of up to 20mg prior to sleeptime.

31 (withdrawn). The pharmaceutical formulation as claimed in claim 15, wherein the instructions for administration instruct a single dose comprising active ingredient of triprolidine of between 0.01 and 20mg prior to sleeptime.

32 (original). A waking refreshed aid as claimed in claim 14, wherein the instructions for administration instruct a single dose of the triprolidine active ingredient of up to 20mg prior to sleeptime.

33 (original). A waking refreshed aid as claimed in claim 14, wherein the instructions for administration instruct a single dose comprising the active ingredient triprolidine of between 0.01 and 20mg prior to sleeptime.

34 (withdrawn). A method as claimed in claim 9, wherein the triprolidine is in the form of triprolidine hydrochloride.

35 (withdrawn). A method as claimed in claim 9, wherein the person is

suffering from a sleep disorder.

36 (withdrawn). A method as claimed in claim 9, wherein the person is not suffering from a sleep disorder but is desirous of achieving a feeling of waking refreshed upon waking.

37 (withdrawn). A method as claimed in claim 9, wherein the active ingredients are administered orally, nasally, optically, rectally, pulmonarily, transdermally or sub-lingually.

38 (withdrawn). A method as claimed in claim 9, wherein the active ingredients are administered in the form of a tablet, capsule, drink, lozenge, drops, emulsion, dry powder, suspension, pastille, patch, suppository, syrup, consumable film such as a buccal wafer, sub-lingual spray or nasal spray.

39 (withdrawn). A method as claimed in claim 9, wherein the active ingredients are administered to the mucous membranes of the nasal cavity.

40 (withdrawn). A method as claimed in claim 9, wherein the active ingredients are administered as a solution or suspension spray or as a powder.

41 (withdrawn). A method as claimed in claim 9 in which the active ingredients are administered between 1 minute and 2 hours prior to sleeptime.

42 (currently amended). Use The method as claimed in claim 1, wherein the triprolidine is in the form of triprolidine hydrochloride.

43 (currently amended). Use The method as claimed in claim 1, wherein the composition is for oral administration.

44 (currently amended). Use The method as claimed in claim 1, wherein the composition is in the form of a tablet, capsule, drink, lozenge, drops, emulsion, dry powder, suspension, pastille, patch, suppository, syrup, consumable film such as a buccal wafer, sub-lingual spray or nasal spray.

45 (withdrawn). Use as claimed in claim 1, wherein the composition is for administration to the mucous membranes of the nasal cavity.

46 (withdrawn). Use as claimed in claim 1, wherein the composition is a solution or suspension or a powder.

47 (currently amended). The ~~use~~ method as claimed in claim 1, wherein the triprolidine forms the active ingredient of a formulation which contains a blend of two or more diluents, one of which may also serve as a disintegrant.

48 (currently amended). The ~~use~~ method as claimed in claim 1, wherein the

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triprolidine forms the active ingredient of a formulation, which comprises a saccharide diluent.

49 (currently amended). The ~~use~~ method as claimed in claim 48, wherein the triprolidine formulation further comprises a disintegrant.

50 (currently amended). The ~~use~~ method as claimed in claim 49, wherein the triprolidine formulation further comprises the saccharide diluent and the disintegrant in the ratio of 1-10 parts by weight ~~saccharide~~ of saccharide diluent to 1 part by weight of disintegrant.

51 (currently amended). The ~~use~~ method as claimed in claim 49, wherein the saccharide diluent is lactose, and the disintegrant is croscarmellose sodium.

52 (currently amended). The ~~use~~ method as claimed in claim 47, wherein the triprolidine formulation further comprises a lubricant.

53 (currently amended). The ~~use~~ method as claimed in claim 52, wherein the lubricant is magnesium stearate.

54 (currently amended). The ~~use~~ method as claimed in claim 47, wherein the triprolidine formulation is formed with a coating of a hydrophilic polymer.

55 (currently amended). The ~~use~~ method as claimed in claim 54, wherein the hydrophilic polymer is a methylated cellulose derivative.

56 (currently amended). The ~~use~~ method as claimed in claim 47, which is free of ingredients intended or effective to sustain or prolong release of the active ingredients.

57 (currently amended). The ~~use~~ method as claimed in claim 1, wherein the dosage of the said further pharmaceutically active agent is one suitable for the treatment selected.

58 (currently amended). The ~~use~~ method as claimed in claim 1, wherein a single dosage form of said pharmaceutically active agent is in the range 0.1mg - 2000mg.

59 (withdrawn). A method of manufacturing a formulation as claimed in claim 45, which involves direct compression of the ingredients into a tablet without an intermediate granulation stage.

60-71 (cancelled).